

### Remarks/Arguments

The foregoing amendments are of formal nature, including cancellation of claims 31, 37-39, and 57-59, and the amendment of claim 36 and 56. The amendment do not add new matter.

Applicants note and appreciate the entry of the Terminal Disclaimed filed on April 11, 2003 resulting in the withdrawal of the earlier double-patenting rejection, and the withdrawal of the earlier objection to the specification as a result of applicants' amendment to the title. Of the claims pending in this application, claims 29, 30, 32-35, 40-48 and 59 have been allowed. Claims 31, 36-39 and 56-59 have been objected to, and claim 36 has been rejected.

#### ***Claim Objections***

A. Claim 31 has been objected to under 37 CFR 1.75(c) for its recitation of recombinant human interferon. The Examiner notes that "it is not known how recombinantly produced IFN differs from non-recombinant IFN since the amino acid sequence for both would be identical regardless of how it is produced."

Without acquiescing in the Examiner's position, and merely to facilitate the prosecution of the present application, claim 31 has been canceled which moots the present objection. Applicants note, however, that the amino acid sequence and other properties, such as glycosylation pattern, of recombinant human interferon may indeed differ from non-recombinant interferon. For example, on page 2, lines 1-12 of the specification applicants clearly explain that recombinant human IFN- $\gamma$  as produced in *E. coli* has 146 amino acids, commencing with the N-terminal sequences of CYS-TYR-CYS, and differs from the non-recombinant, "native" form, which lacks these three N-terminal amino acids.

B. Claim 36 has been objected to under 37 CFR 1.75(c) for its recitation that the patient treated is at risk of developing cardiac hypertrophy. According to the

rejection, this claim expanded the subject group defined in claim 29, on which claim 36 depends. Applicants refer to the definition of "treatment" on page 11, lines 20-24 of the specification, which includes "prophylactic and preventative measures." Therefore, claim 36 does not expand the scope of claim 29, and applicants respectfully request the withdrawal of the present objection.

C. Claims 56-58 have been rejected under 37 CFR 1.75(c). The Examiner notes that it is "unclear how these claims differ from claim 29 since it seems inherent that a person having cardiac hypertrophy (as recited in claim 29) would have increased levels of PGF1 $\alpha$ , . . . [and] it appears that the causes of hypertrophy in claim 29 do not require a virus."

Claim 56 has been amended, and is not dependent on claim 29. The amendment removed the reference to increased levels of PGF1 $\alpha$ , but retained the recitation that the hypertrophy associated with hypertension is other than hypertrophic cardiomyopathy. There are reports in the art that hypertrophic cardiomyopathy may be, at least partially, of viral origin. Therefore, claim 56, as currently amended, further limits the scope of claim 29, and the present objection should be withdrawn.

#### ***Claim Rejection - 35 USC § 102***

Claim 36 has been rejected under 35 USC 102(e) "as being anticipated by Trigoe et al. (U.S. Patent No. 6,207,641)." Trigoe et al. teach pharmaceutical compositions for treating IFN-related diseases (Example 1). The Examiner notes that "the process step of administering IFN are the same regardless of whether or not the purpose is to treat cardiac hypertrophy."

Claim 36 has been amended to recite that the patient is identified as being at risk of developing cardiac hypertrophy prior to treatment. Trigoe et al. has no disclosure or suggestion for the use of IFN- $\gamma$  to treat cardiac hypertrophy, or the identification of patients who are at risk of developing cardiac hypertrophy. Accordingly, Trigoe et al.

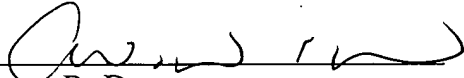
does not anticipate claim 36, and the Examiner is respectfully requested to withdraw the present rejection.

All claims are believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney Docket No.: 39766-0068A2D1). Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: March 30, 2004

  
Ginger R. Dreger  
Reg. No. 33,055

**HELLER EHRMAN WHITE & McAULIFFE LLP**

**Customer No. 25213**

275 Middlefield Road

Menlo Park, California 94025

Telephone: (650) 324-7000

Facsimile: (650) 324-0638

SV 2006207 v1  
3/29/04 4:10 PM (39766.0068)